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BDB

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Koziel et al.
Serial No. : 09/988,462
Filed : November 20, 2001
For : Synthetic DNA Sequence Having Enhanced
Insecticidal Activity In Maize
Examiner : E. McElwain
Group Art Unit : 1638

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**INFORMATION DISCLOSURE STATEMENT
BEFORE MAILING OF A FIRST OFFICE ACTION**

February 11, 2003

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Applicants submit this communication and the attached Form PTO-1449 in compliance with 37 C.F.R. §§1.56, 1.97 and 1.98. A copy of each of the documents listed on the accompanying Form PTO-1449 is submitted herewith.

This Information Disclosure Statement (hereafter "IDS") is being filed before the mailing date of a first Office Action on the merits according to 37 C.F.R. §1.97(b)(3). Therefore, no fees are due in connection with this filing. However, should any fees be deemed necessary in connection with this filing, the Assistant Commissioner is hereby authorized to charge Deposit Account No. 23-1703.

This IDS is submitted to provide the Examiner with copies of prior art cited in the following patents and applications that are related to the instant application:

Parent application Ser. No. 09/547,422, filed Apr. 11, 2000, now **U.S. Pat. No. 6,320,100**, issued Nov. 20, 2001, which is a continuation of U.S. application Ser. No. 08/459,504, filed Jun. 2, 1995, now **U.S. Pat. No. 6,075,185**, which is a division of U.S. application Ser. No. 07/951,715, filed Sep. 25, 1992, now **U.S. Pat. No. 5,625,136**, which is a continuation-in-part of U.S. application Ser. No. 07/772,027, filed Oct. 4, 1991, now abandoned; and

Application Ser. No. 10/136,998, filed April 30, 2002, pending, which is a continuation of Ser. No. 08/438,666, filed May 10, 1995, now **U.S. Pat. No. 6,403,865**, issued June 11, 2002, which is a continuation of Ser. No. 08/008,374, filed Jan. 25, 1993, now abandoned, which is a continuation-in-part of both: (a) Ser. No. 07/951,715 filed Sep. 25, 1992, now **U.S. Pat. No. 5,625,136** issued Apr. 29, 1997, which is a continuation-in-part of Ser. No. 07/772,027 filed Oct. 4, 1991, and (b) Ser. No. 07/659,433 filed Feb. 25, 1991, now abandoned, which is a continuation-in-part of Ser. No. 07/573,105, filed on Aug. 24, 1990, now abandoned.

This prior art is identified at pages 1-3 of the attached Form PTO 1449.

The IDS is also submitted to provide the Examiner with information arising out of an allegation of unenforceability in a patent infringement litigation entitled, *Syngenta Seeds, Inc. v. Monsanto Company; DeKalb Genetics Corp.; Pioneer Hi-Bred International, Inc.; Dow Agrisciences, LLC and Mycogen Plant Science, Inc. and Agrigenetics, Inc.*, C.A. No. 02-1331 (D. Del.). In the litigation, Plaintiff Syngenta Seeds, Inc. (the exclusive licensee of Syngenta Investment Corp., the assignee of the present application) has asserted that defendants infringe U.S. Patent Nos. 6,320,100; 6,075,185; and 6,403,865 (the '100, '185, and '865 patents, respectively), which are related to the present application in that they claim benefit 35 U.S.C. § 120 from parent application Ser. No. 07/951,715, filed Sep. 25, 1992, now U.S. Pat. No. 5,625,136, which is a continuation-in-part of U.S. application Ser. No. 07/772,027, filed Oct. 4, 1991, now abandoned.

Defendants Monsanto Company, DeKalb Genetics Corp. and Pioneer Hi-Bred International, Inc. have asserted that the '100, '185 and '865 patents are unenforceable because patentee allegedly intentionally withheld material information from the Patent and Trademark Office. Enclosed are copies of the following pleadings from the litigation, each of which sets forth the defendants' allegations of unenforceability:

Monsanto's and DeKalb's First Amended Answer and Counterclaim to the Complaint;

First Amended Answer, Affirmative Defenses and Counterclaims of Pioneer Hi-Bred International, Inc.

These pleadings assert that patentee withheld material prior art in three areas:

(i) information concerning the work of Kenneth Barton and Michael Miller while they were employed by Agracetus, Inc. on codon modified Bt genes using plant preferred codons as reflected in U.S. Patent Application Serial No. 390,561, filed August 7, 1989 (hereafter "the Barton & Miller Work")

(ii) information concerning work of Chuck Armstrong at Monsanto Company on the expression of Bt genes in corn plants as reflected in a presentation entitled, "Production of Transgenic Corn Plants Resistant to the European Corn Borer" at the American Society of Agronomy Meeting in March 1991 (hereafter "the Armstrong Work");

(iii) information concerning the Bt11 corn seed products sold by Syngenta (hereafter "Bt11").

This IDS provides the Examiner with information relating to each of these areas as outlined below. This submission should not be misconstrued as an acknowledgement by applicants or the undersigned that any of the submitted information is material or qualifies as prior art.

1. The Barton and Miller Work

In *Monsanto Company v. Mycogen Plant Science, Inc. and Ciba Geigy Corporation*¹, C.A. No. 96-133 (D. Del.), certain claims of Monsanto's U.S. Patent No. 5,500,365 (hereafter "Monsanto's '365 patent") concerning synthetic genes modified to enhance expression of the protein in plants were found invalid at trial under 35 U.S.C. § 102(g) in view of the prior invention of Barton and Miller. The allegation was supported by various evidence, including a copy of Barton and Miller's U.S. Patent Application No. 07/390,561, filed August 7, 1989 (which is also U.S. Pub. No. US2001/0003849, published June 14, 2001), trial testimony of Kenneth Barton, Michael Miller, and Sandra Cannon and other information set out at page 9 of the attached PTO Form 1449.

The jury at trial found that the allegedly infringed claims were invalid in view of the Barton and Miller Work. Monsanto thereafter moved for judgment as a matter of law contending that there was no legally sufficient evidentiary basis for a reasonable jury to find that the claims were invalid due to the prior invention of Barton and Miller. The U.S. District Court for the District of Delaware denied Monsanto's motion in a published decision (61 F. Supp.2d 133). The Court of Appeals for the Federal Circuit affirmed in a published decision (261 F.3d 1356). Copies of the published decisions from the District Court and the Court of Appeals are also identified at page 9 on the attached Form PTO 1449.

2. The Armstrong Work

In *Novartis Seeds, Inc.*² v. *Monsanto Company and DeKalb Genetics Corp.*, C.A. No. 97-39, 40 (D. Del.), the plaintiff Novartis asserted that the defendants were infringing U.S. Patent

¹ Ciba Geigy Corporation is a predecessor of an affiliate of assignee of the present application.

² Novartis Seeds, Inc. is a predecessor of an affiliate of the assignee of the present application.

No. 5,595,733, which concerns methods of controlling insect larvae. As part of its defense at the trial of the litigation, defendant Monsanto presented testimony of Charles Armstrong, Michael Fromm, Frederick Perlak, David Fischhoff and Thomas Klevorn concerning work on expression of synthetic Bt genes in corn performed at Monsanto Company in the early 1990s. The testimony of Charles Armstrong, Frederick Perlak, and David Fischhoff (and exhibits thereto) is identified at pages 10-11 of the attached Form PTO 1449. The testimony of Michael Fromm and Thomas Klevorn was previously submitted to the PTO in a related application and is identified at page 7 of the Form PTO 1449.

Mr. Armstrong testified that this work was presented at the American Society of Agronomy Meeting in March 1991 and an abstract was published for the presentation. (See Trial Testimony of Charles Armstrong, *Novartis Seeds, Inc. v. Monsanto Co. & DeKalb Genetics Corp.*, p. 1276-77; and Defendant's Trial Exhibit 2286, enclosed herewith). During his testimony, Mr. Armstrong also relied on a notebook record (Defendant's Exhibit 2154-A, enclosed herewith) to show his work in transforming corn. The notebook record identifies the plasmid used in the Armstrong experiment as pMON10902. (See Defendant's Exhibit 2154-A).

Monsanto's U.S. Patent No. 5,500,365, which was not at issue in this litigation, provides a description of the plasmid designated pMON10902. The '365 patent describes the gene in pMON10902 as a "synthetic full length B.t.k. HD-73" gene (See the '365 patent, Example 8 at Col. 36 and in Fig. 11).

This IDS provides copies of the aforementioned testimony and exhibits relating to the Armstrong work.

3. Bt11

In *Plant Genetics Systems v. Novartis Seeds, Inc.*, C.A. No. 96-459 (D. Del.) and *Novartis Seeds, Inc. v. Monsanto Company and DeKalb Genetics Corp.*, C.A. No. 97-39, 40 (D. Del.), testimony and documentary exhibits were provided regarding the development of the corn seed sold under the name Bt11, developed by Sandoz Crop Protection and Northrup King Company (both of which are predecessors of affiliates of assignee of the present application, and which are hereafter collectively referred to as Sandoz). Sandoz developed the Bt11 product under separate contracts with Monsanto (which provided a Bt gene) and Hoechst AG, a German company (which performed corn protoplast transformation experiments in Germany). The information regarding the development of Bt11 is identified at pages 12-13 of the attached Form PTO 1449.

Bt11 contains a truncated HD-1 Bt gene provided to Sandoz by Monsanto in a plasmid designated pMON5377, which Sandoz was not permitted to analyze. Monsanto's U.S. Patent No. 5,500,365, which was not at issue in either of the aforementioned litigations, provides a description of the plasmid designated pMON5377 at Example 2, Cols. 19-20.


Sandoz excised the Bt gene from the pMON5377 plasmid and included the gene in an expression cassette developed by Sandoz. Sandoz provided the Sandoz cassette/Monsanto gene in a plasmid designated pZO1502 to Hoechst AG in Germany pursuant to a service contract, under which Hoechst was not permitted to analyze the plasmid. From the testimony, it appears that scientists at Hoechst AG in Germany transformed a proprietary corn cell line designated He89 using a protoplast technique with the Sandoz plasmid pZO1502. Hoechst apparently regenerated transformed corn plants from the He89 cell line and thereafter crossed those

transformed plants with inbred germplasm provided to Hoechst by Sandoz. Hoechst later sent corn seed resulting from the cross to Sandoz in the United States.

This IDS provides copies of certain testimony and documents relating to the development of Bt11.

The Commissioner is authorized to charge any fee required in connection with this submission to Deposit Account No. 23-1703.

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "John Scheibeler", written over a horizontal line.

John Scheibeler
Reg. No. 35,346
Attorney for Applicants

Customer No. 007470
(212) 819-8830

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UNITED STATES PATENT DOCUMENTS

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FORM PTO-1449 (REV. 2-82) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Atty. Docket No.	Serial No.
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OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages, Etc.)

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	Perlak et al., <i>Proc. Natl. Acad. Sci. USA</i> , 88:3324-3328 (1981).
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UNITED STATES PATENT DOCUMENTS

*Examiner Initial	Document No.								Date	Name	Class	Sub- Class	Filing Date, if Appropriate
	6	4	0	3	8	6	5		06/11/2002	Koziel et al.			
	6	3	2	0	1	0	0		11/20/2001	Koziel et al.			
	6	3	3	1	6	6	5		12/18/01	Lundquist et al.			

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	Kim et al., A 20 nucleotide upstream element is essential for the nopaline synthase (nos) promoter activity (1994) Plant Mol. Biol. 24(1):105-117.
	Harper et al., Calcium and lipid regulation of an Arabidopsis protein kinase expressed in Escherichia coli (1993) Biochemistry 32(13): 3282-3290.
	Murray et al., Analysis of unstable RNA transcripts of insecticidal crystal protein genes of Bacillus thuringiensis in transgenic plants and electroporated protoplasts (1991) Plant Mol. Biol. 16:1035-1050.

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UNITED STATES PUBLISHED PATENT APPLICATIONS

*Examiner Initial	Document No.	Date	Name	Class	Sub- Class	Filing Date, if Appropriate
	2 0 0 1 0 0 0 3 8 4 9	6/14/01	Barton et al.	800	279	4/17/98

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	Published opinion – <u>Monsanto v. Mycogen Plant Science, Inc.</u> , 261 F.3d 1356 (Fed. Cir. 2001)
	Published opinion – <u>Monsanto v. Mycogen Plant Science, Inc.</u> , 61 F. Supp. 2d 133 (D. Del. 1999)
	Trial Testimony – <u>Monsanto v. Mycogen & Ciba Geigy</u> , Civil Action No. 96-133 (RRM), pp. 120-137
	Trial Testimony of Kenneth Barton – <u>Monsanto v. Mycogen & Ciba Geigy</u> , Civil Action No. 96-133 (RRM), pp. 1047-1066
	Trial Testimony of Michael Miller– <u>Monsanto v. Mycogen & Ciba Geigy</u> , Civil Action No. 96-133 (RRM), pp. 1097-1110
	Trial Testimony of Sandra Cannon – <u>Monsanto v. Mycogen & Ciba Geigy</u> , Civil Action No. 96-133 (RRM), pp. 1110-1125
	Trial Testimony – <u>Monsanto v. Mycogen & Ciba Geigy</u> , Civil Action No. 96-133 (RRM), pp. 2207-2228 and 2689 – 2701
	30(b)(6) Statement made by Monsanto concerning the Barton and Miller work, read into the record at the trial of <u>Monsanto v. Mycogen & Ciba Geigy</u> , Civil Action No. 96-133 (RRM), pp. 1307-1312
	Excerpts from Michael J. Miller notebook 366
	Excerpts from Ken Barton notebook 156
	Excerpts from Sandra Cannon notebook 323
	Excerpts from Sandra Cannon notebook 316
	Excerpts from Sandra Cannon notebook 413
	Excerpts from Michael Miller notebook 404
	Improved Expression of Genes in Plants
	Agracetus Research and Development Report: Third Quarter, 1988

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	Trial Testimony of Irv Mettler- <u>Novartis v. Monsanto</u> , Civil Action No. 97-39 & 97-40, pp. 2299-2336
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	Trial Testimony of Irv Mettler- <u>Plant Genetics Systems v. Northrup King</u> , Civil Action No. 96-459, pp. 850-957
	Trial Testimony of Ed Resler - <u>Novartis v. Monsanto</u> , Civil Action No. 97-39 & 97-40, pp. 733-741
	Trial Testimony of Stephen Evola - <u>Novartis v. Monsanto</u> , Civil Action No. 97-39 & 97-40, pp. 399-526
	Trial Testimony of Stephen Evola - <u>Monsanto v. Mycogen & Ciba Geigy</u> , Civil Action No. 96-133 (RRM), pp. 827-891
	Trial Testimony of Thomas Klevorn - <u>Monsanto v. Mycogen & Ciba Geigy</u> , Civil Action No. 96-133 (RRM), pp. 262-264
	Trial Testimony of David Fischhoff - <u>Monsanto v. Mycogen & Ciba Geigy</u> , Civil Action No. 96-133 (RRM), pp. 1953-1955
	Agreement between Monsanto Company and Sandoz for Development of Insect Resistant Corn
	Excerpts from Palo Alto Plant Biotechnology Report: First Quarter, 1989 (DX 2665)
	ZRB Project Meeting (DX 2281)
	Modification of the Research Agreement Between Monsanto Company Sandoz. (DX 2269)
	PAB-6 Technical Report (DX 2266)
	PAB-10 Bt Insect Resistance (DX 2284)
	DNA Samples and expressions cassettes for expression of B.T. toxin protein and PAT
	Samples of Northrup NK-A and NK-B to be used in backcrosses.
	Shipment of 10 best frozen leaf tissue from each experiment for crossing to NK-A and NK-B lines.
	Report on Maize transformation experiments with Sandoz plasmids 1502 and 1503.
	Letter from G. Donn to Irvin Mettler regarding shipment of leaf samples
	Plants from transformants Nr. 1502-1, 1503-2, 1502-11 and 1503-3, 1503-7 will follow soon (DX 2286)
	Letter from Gunter Donn to Irvin Mettler regarding shipment of leaf samples (DX 2285)
	Facsimile from Irvin Mettler to Ron Meeusen referencing facsimile from Mettler to Donn regarding ELISA assays (PX278)

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OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages, Etc.)

	Stanton Biotechnology – October Highlights (PX194)
	Facsimile from Irvin Mettler to Gunter Donn regarding ELISA assays and the collection of additional plant organ samples (PX195)
	Northrup King Biotechnology Report (DX 2256)
	Minutes of the Bt (MDMV) Corn Planning Meeting, Stanton, Minnesota
	Biologische Forschung, Bereich C, H 872 N
	PAB-10 Bt Insect Resistance Fourth Quarter Report (DX 2288)
	Fourth Quarter Report of Plant Biotechnology
	Cover letter from G. Donn to I. Mettler with enclosures lyophilized leaf samples from 1502 plants. (PX281)
	Facsimile from Gunter Donn to Ron Meeusen regarding field testing (PX640)
	Facsimile from Irving Mettler to Gunter Donn regarding ELISA assays (PX282)
	Facsimile from G. Donn to L. Murry re western analysis
	Facsimile from G. Donn to R. Meeusen re: the shipment of maize seeds to the APHIS-inspection station.
	Facsimile from G. Donn to R. Meeusen re: shipment of seeds sent
	Plant Biotechnology Report: Third Quarter, 1992
	Transgenic Project #1 (DX 2255)
	B.T. Corn NK 1996 Product (PX382)
	Summary of bioactivity assays of contrasformed BMS calli (conducted July 11 & August 1, 1990). Insect assay with 1str instar Manduca sexta larvae (0 to 6 hours old), five per plate. Assays conducted and scored by D. Cerf. (DX 2282)
	Research Highlights – Novel Genetics (PX20)

Examiner:

Date Considered:

*Examiner: Initial citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.